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FDA Regulation of Quack Devices: It's a Miracle!...or Is It?

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It's a Miracle!..., or Is It?

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I. Introduction

Medical devices that presented substantial deception or an unreasonable and substantial risk of illness or injury have existed since the inception of this country. Even our forefathers such as Ben Franklin were subjected to these quack devices. It was not until the country's bicentennial, however, that explicit statutory provisions were enacted to allow the Food and Drug Administration (the FDA) to ban quack devices. Even though active legislative steps have now been taken to regulate these useless medical devices, the problem continues to grow. This paper is an examination of the steps Congress and FDA have taken to regulate quack devices, where the organizations went wrong, and what should be done in the future.

II. Historical Background

Prior to the enactment of Section 516 of the Federal Food Drugs and Cosmetic Act (the Act), the American public had no direct statutory protection against quack devices . Consequently, they ran virtually unchecked. These devices ranged from relatively harmless gadgets such as audio tapes that promised to remove warts through self-hypnosis, to potentially more dangerous machines such as Albert Abrams' Radioscope which purported to diagnose and heal patients based on the machine's analysis of dried

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blood specimens that were sent to Abrams. Once the blood specimens were inserted into the Radioscope, the diagnosis was sent to patients along with recommended settings for treatment with other Abrams machines.¹

Quack devices such as the hypnotic tapes for warts were relatively harmless in that they did not subject patients to serious health risks from nontreatment of ailments. These gadgets often dealt with physical appearance and their greatest harm to consumers was usually economic loss. Although the economic harm done to each individual consumer may not have been great, each year millions of dollars were spent on these worthless devices by the American public, as a whole. Inventions like the Radioscope which claimed to treat much more serious afflictions often had much more grave results on patients. Often, the treatment itself was harmful to users. For example, many users of quack contraceptives were the victims of genital infections and injuries.² In other cases, the harm stemmed from a lack of legitimate treatment. Customers who put their faith in these gadgets often delayed getting legitimate medical attention. These delays usually resulted in heightened severity of the illness and, sometimes, death.

Although the FDA was able to take steps against these quack devices, it often had to do so under convoluted and complicated procedures. Many times the agency pursued devices as drugs because the concepts were similar and the statutory provisions on drugs were much more developed and stringent than those on

I Hutt, Peter Barton and Merrill, Richard A. Food and Drug Law. Foundation

Press, Inc. (1991), pp. 721 and 725

² Hutt, p.735

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devices.³ As devices became increasingly more sophisticated,

however, FDA found it more difficult to prove that certain devices should be prohibited. It became apparent that explicit provisions in the act were necessary in order to deal with quack devices more effectively.

III. The Medical Device Amendments of 1976

In 1976 Congress was finally able to promulgate amendments to the Federal Food, Drug, and Cosmetic Act which allowed for effective regulation of quack devices. Section 516 of the Act provides:

Sec. 516. [360f] (a) Whenever the Secretary finds,

on the basis of all available data and information, that—

(1) a device intended for human use presents substantial deception or an unreasonable and

substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

See e.g. United States v. An Article of Drug... Bacto-Unidisk

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The Banned Devices provision dramatically expanded

the power of the FDA in controlling quack devices. Before the legislation was passed, FDA's power over such devices was limited to injunction and seizure actions against manufacturers of these products. In each of these actions, FDA had the burden of proving that the devices were misbranded or adulterated pursuant to sections 302 and 304 of the Act. The product was also allowed to remain on the market as long as the proceeding lasted. Once section 516 was enacted, however, the process of regulating devices became much easier. Once a device was labeled a banned device in accordance with section 516, FDA no longer had to continuously prove that the device was misbranded or adulterated. The agency needed only show that the device had been banned. Furthermore, under the Special Effective Date provision of section 516, FDA could remove the product immediately upon notice of a regulation, if the commissioner determined that the use of the device present[ed] an unreasonable, direct, and substantial danger to the health of individuals.⁴

IV. Contemporary Quack Devices

With the increased facility of regulating quack devices, one would expect to see a dramatic increase in the amount of devices that were regulated. Since the promulgation of the banned device provision, however, there has been only one regulation and it was made more than ten years ago. This was a regulation banning

42 Fed. Reg. 42000 (August 19, 1977)

prosthetic hair fibers intended for implantation into the human scalp to simulate natural hair or conceal baldness.⁵ Although the regulations banning prosthetic hair fibers

alleviated a serious problem that affected a significant amount of people, they were by no means dispositive of the problem of quack devices. In fact, this problem is soaring to an all-time high. In a joint congressional subcommittee hearing on Recent Trends in Dubious and Quack Medical Devices, the subcommittees found that healthcare fraud was expected to cost the Nation \$70 billion in 1992, and as much as \$100 billion by 1995, a figure greater than the total take of organized crime.⁶

The same range of devices that existed before 1976 continues to exist. Now, instead of hypnotic, wart-removing tapes, we have the Hyperemiator which promises to increase the length and diameter of any penis. The advertisement even coins FDA terminology by claiming that the device has been tested thoroughly by thousands of users and is proven *effective and safe*. A similar product with potentially much more dangerous repercussions is the Control-X, which is said to ensure that you climax only when you want to. The advertisement says that the device is completely safe and exclaims, in bold letters, NO CONDOMS! The ad is legitimized by the equally boldly-typed claim that the device is doctor developed. Even if Control-X does what it says, the dangers associated with it are intolerable. Improper use of the device

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49 Fed. Reg. 1177 (January 10, 1984)

6 Recent Trends in Dubious and Quack Medical Devices. Small Business Serial No. 102-7 1. Aging Comm. Pub. No. 102-877. 102nd Cong., 2d Sess. (1992), p.¹

would lead to significantly increased risks of pregnancy, and the advocacy of no condoms presents serious health risks in the face of sexually transmitted diseases such as AIDS.

Quack devices are by no means limited to advertisements found in the back of adult magazines. We also have our present day versions of the Radioscope. The Sweep Pulse Resonator is a device that is promoted to cure anything, including arthritis, cancer and AIDS. A little bottle of water and alcohol is inserted into a hole in the device and then a practitioner connects the patient to the device with an electronic lead. Information about the patient is then fed into the device, and it is said to electronically calibrate and charge the water and alcohol solution. The patient then drinks the solution over a period of time or rubs it on his or her skin and is cured. Once the patient has been attached to the machine he or she does not have to return to the clinic when the solution is exhausted. The patient simply sends a personal photo which is inserted into the Sweep Pulse Resonator and the machine does the rest.⁷

An example of the grave results use of such devices as the Sweep Pulse Resonator can have is found in a story about a woman who visited the Paradise Pain Clinic in Las Vegas. The woman had been diagnosed with a cancerous lump in her left breast. She feared surgery, so she consulted with a man who ran a clinic where he claimed he could cure cancer. The cancer treatment consisted of hooking the woman up to a machine that generated low current electricity by means of electrodes hooked directly to various points

⁷ Recent Trends..., p.2

of here body as she sat in a chair. After the first night of treatment, the woman suffered bleeding from nearly every orifice that she had. She was told that this meant that the system was working and that it was exploding the cancer cells. Soon the woman also began developing puffy and infected sores where the electrodes were attached. After approximately 6 months of treatment, the head of the clinic called the woman and told her that she was completely cured. When her family finally convinced her to see another doctor, it was found that she had several other cancerous tumors in her body, including one in her skull above her eye, one the size of a golf ball behind her other eye, multiple tumors in her breasts, and several in her legs. At the point of her initial diagnosis with cancer, the condition was treatable. After her treatment at the Paradise Pain Clinic, it was not. Before dying two months after she was told that she was completely cured, the woman lost her ability to walk and talk.⁸

At first, one might think that this woman was an exception and the epitome of the ignorant, the unthinking, and the credulous, but that perception might change if one knew that this was the mother of a licensed practical nurse who desperately pleaded with her mother to see another doctor. Perhaps, a better explanation is that, often, the people who are most susceptible to quack devices are the ones who are in the most need of protection. People who are victims of deadly or painful diseases like AIDS, cancer, and arthritis are desperate to find cures for these diseases. This may cause them to do things and place faith in devices that

⁸ 'Recent Trends...', p.7-9

might seem absurd to those who are not afflicted with these illnesses. These people are also more apt to be under emotional strain that keeps them from weighing options as carefully as they may have in the past. Whatever, the reasons may be for their susceptibility to quack devices, Congress and FDA have a responsibility to protect these people that has not been fulfilled. In addition to protecting those who may suffer serious health problems because of use of quack devices, the staggering amounts spent on these devices show that these organizations need to take a tougher stance on quack devices, in general.

V. **Locating the Problem**

In order to determine where the intention of Congress and FDA to impose stricter regulations on quack devices diverges from actual action, we must examine the banned devices provision of the Act more closely. A problem with the statute may be that the criteria that it sets for the FDA to ban a device is too high. The statute says that a device can only be banned if it presents a substantial deception or an unreasonable and substantial risk of illness or injury. The legislative history of section 516 defines substantial as important, material, or significant.⁹ These terms do little to elucidate the substantial requirement. If history is any indication, however, courts will interpret provisions of the Act broadly, so that the FDA can effectuate the purpose of the act.¹⁰

~ 42 Fed. Reg. 42000

10 See e.g. United States v. Undetermined Quantities of Article of Device

Thus, it is unlikely that fear of not being able to sustain the claim that a device presents a substantial deception or risk of illness or injury is what impedes FDA from issuing more regulations against quack devices.

Another possible deterrent to more FDA regulations might be the evidentiary requirements of the statute. Before issuing a regulation, FDA must find, on the basis of all available data and information, that substantial deception or risk of illness or injury exists.¹ I This means that FDA must conduct extensive research on a device prior to issuing a regulation or even sending a warning letter to a manufacturer. This research includes, but is not limited to, consultation with panels of experts on the device, consideration of evidence submitted by the manufacturers, and review of any information the agency finds in its own investigations.¹² Such an undertaking would require much of the time and resources allocated to the FDA, and the possibility would remain that the manufacturer could simply make a few changes in order to leave the device on the market.

This line of reasoning might apply to quack devices like the Hyperemiator which cause little more than economic loss to consumers. It is difficult to believe, however, that devices like the Sweep Pulse Resonator and the device used at the Pleasure Pain Clinic do not pose great enough dangers to society to merit a good deal of the FDA's time and resources. Furthermore, it is highly likely that such dangerous devices would qualify under part (b) of

section 516 as presenting an unreasonable direct, and substantial danger to the health of individuals, thus allowing FDA to ban the devices before regulations became final. Surely these devices and others like them are equally dangerous to society as prosthetic hair fibers.

The most likely reason that FDA has only promulgated one regulation since the enactment of section 516 is that the agency realizes the regulations approach, as it is currently administered, is not an effective means of dealing with the quack device industry. There are two problems with the current congressional and FDA approach.

First, ideally, regulations serve two purposes: 1. they provide a warning to manufacturers that problems exist in their devices 2. they prohibit the further manufacture and distribution of the unchanged quack devices. The problem with these purposes is that they are based on the premise that these devices are manufactured by people who legitimately believe in their product. In reality, quack devices are often made and disseminated by people who are perfectly aware that their product does not do what it claims. Thus, instead of helping a manufacturer correct a problem of which it may not have been aware, the warnings comprised in regulations often only serve to tell a crook that he or she has been caught and that it's time to relocate. In his testimony before Congress on the Recent Trends in Dubious and Quack Medical Devices, Randall Everitt, a criminal investigator for the Idaho office of the Attorney General, spoke to this issue:

13 Recent Trends..., p.15

14 Recent Trends..., p.35

[The FDA] will send letters of requests for information or letter to some of these practitioners to cease and desist their operations. To me, that's a clear warning that that practitioner or that fraudulent doctor either moves someplace else or covers up.¹³

Often the manufacturer is content with his or her previous earnings, and he or she has no need or desire to continue manufacture of the devices. Thus, the second purpose of regulations, prohibiting the further manufacture and distribution of unchanged quack devices, is also misplaced on the quack device industry.

The second problem with the current congressional and FDA approach to banning quack devices is that FDA does not have enough resources allocated to the pursuit of quack devices even if it wants to issue a regulation banning a device. In his testimony before Congress, Ronald M. Johnson, Director of the FDA Office of Compliance and Surveillance, Center for Device and Radiological Health, stated that there were only 7 full-time employees out of 1100 nationwide who were devoted to medical device fraud.¹⁴ This testimony is proof that regulation of quack devices is very low in the FDA's regulatory priorities.

VI. A Proposed Solution

The solution to this country's problem with quack devices is by no means revolutionary. The simple fact is that either Congress needs to allocate more resources to the FDA, so that it can achieve

the goals that Congress intended with section 516, or the FDA must redistribute its resources so that more people and money are allocated to this issue. Section 516 was a tremendous move in the right direction toward regulation of quack devices. FDA, however, does not have enough resources to administer it properly.

Regulations are a better means of controlling quack devices than actions in court. Court actions are often long and protracted and force the FDA to sustain a burden of proof that exhausts many resources. Regulations, although requiring resources during the investigation of the product, often go unchallenged and are, ultimately, less taxing on the agency. Regulations, however, must be administered properly in order to be effective.

It was stated earlier that regulations serve two purposes: 1. they provide a warning to manufacturers and 2. they prohibit the manufacture of the device in the future. If greater resources are allocated to regulation of quack devices, these purposes can take on a whole other meaning than they do currently. With the proper resources the purposes of regulations work together. In order to truly minimize the existence of quack devices, the FDA must create some sort of deterrent to potential manufacturers of the devices. One method would be to require pre-market approval of new devices, similar to new drug requirements. This approach, however, is virtually impossible considering the already too small amount of FDA resources.

Another deterrent that would be possible without the need for such a great increase in resources is stronger stances against these devices. If the FDA were able to conduct more searches and

seizures of quack devices, manufacturers would have less incentive to create these devices and even less courage to stay in a business once they were discovered. Thus, by actually prohibiting the manufacture of these devices, a warning would be given to those who had ideas of producing these gadgets.

The final and most cost effective approach that FDA could take would be to disseminate information to the general public which allows people to make more informed decisions on devices that they buy. FDA could issue guidelines on what to look for in a quack device and general tips on targeted groups by quack device manufacturers and suspect types of devices. This approach, however, would also be the least effective for protecting the ignorant, the unthinking, the credulous, and those who had little hope in conventional medical devices.

VII. Conclusion

The problem of quack devices continues to grow. Just yesterday, the Federal Trade Commission released information stating that claims made by manufacturers of The Miracle-Ear Clarifier were false. This was a product that has affected the lives of hundreds of thousands, if not millions, of people. As long as the current regulatory approach by the FDA is continued, more and more people will suffer the effects of this form of organized crime.